

REMARKS/ARGUMENTS

Claims 3 and 13-18 are pending in the application and stand rejected. The applicants have amended claims 15, 16 and 18. Claims 19-22 are new. No new matter is added by the amendments. Support for the amendments can be found in the specification as filed. In view of the foregoing amendments and following discussion, the applicants submit that all pending claims are in condition for allowance.

On page 2 of the Office Action the Examiner maintained the rejection of claims 3 and 3-17 under 35 U.S.C. § 103(a) as being unpatentable over Anderskewitz et al. (U.S. Patent No. 5,731,332) in view of Gregory et al. (U.S. Patent No. 6,172,096). The applicants respectfully traverse the rejection. Claim 3 recites “a pharmaceutical composition for the treatment of inflammation consisting essentially of the compound of formula (IA) [structure of formula (IA)] and meloxicam of formula [structure of meloxicam] or a pharmaceutically acceptable salt thereof, and a pharmaceutically acceptable carrier or excipient, wherein the composition has a weight ratio of formula (IA) to meloxicam of 1:20”. The specification shows, and the Examiner acknowledges, unexpected results for the composition in a 1:20 ratio in Example 2. However, the Examiner alleges that the “unexpected results, however, have only been shown where the actives were employed in a ratio of LTB4 antagonist:meloxicam of 1:20 and also when administered in a range of rates of administration which varied and were from 0.1 mg/kg formula IA / 2 mg/kg meloxicam to 0.8 mg/kg formula IA / 16 mg/kg meloxicam”. The applicants submit that the claimed ratios are fully supported by the example in the specification and the limitation “wherein the composition has a weight ratio of formula (IA) to meloxicam of 1:20” It is clear from the data in tables 2-3 on pages 13-15 of the specification that regardless of the actual amount (i.e., mg or mg/kg) of the actives administered, as long as the combination treatment of formula (IA) to meloxicam is administered in a weight ratio of 1:20, this combination is unexpectedly and significantly more effective than even higher doses of either compound alone.

The applicants are not limited to only the exemplified dosages in the application. The species here is more than sufficient written description support for the claimed genus including that species. *See, Bilstad v. Wakalopoulos* 386 F.3d 1116, 1124 (2004). The exemplified dosages are sufficient to show that the unexpected results at a weight ratio of 1:20 (formula (IA) to meloxicam) would be predictable over the claimed scope of dosages and would enable a skilled

artisan to make and use the invention without undue experimentation. This is not a case where there is any unpredictability such that the applicant's description would not convey to one skilled in the art knowledge the applicants invented a composition that works for the full range of possible therapeutic dosages. *See, id.* A skilled artisan would have a reasonable expectation of success that the administration of the 1:20 ratio of formula (IA) to meloxicam would be achieved at dosage amounts beyond those that are instantly exemplified because the skilled artisan would be able to take into consideration the different body weights of the patients and adjust accordingly the actual therapeutically effective dosage amounts of the active ingredients accordingly.

The applicants submit the claimed composition would not be obvious to a skilled artisan because the prior art does not direct a skilled artisan to the composition at the claimed weight ratio which creates the unexpected result regardless of the actual administered dose. In light of the above amendments and discussion claims 3 and 13 are not obvious over Anderskewitz et al. in view of Gregory et al. and are therefore allowable. Claims 14-18 which depend from claim 3 and recite further limitations are also not obvious and are thus allowable. Accordingly the applicants respectfully request the Examiner withdraw the rejection.

In view of the foregoing, the Applicants submit that all claims are in condition for allowance. Accordingly, both reconsideration of this application and its swift passage to issuance are earnestly solicited. The fee for a RCE is included herewith. In the event that there are any fees dues and owing in connection with this matter, please charge the same to our Deposit Account No. 11-0223.

Dated: August 18, 2008

Respectfully submitted,

By: s/Timothy X. Gibson/
Timothy X. Gibson, Reg. No. 40,618
Attorney for Applicant(s)

Patent Department
Boehringer Ingelheim Corp.
900 Ridgebury Road
P.O. Box 368
Ridgefield, CT 06877
Tel.: (203) 798-4868